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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/328,165 10/24/94 MASTERSON

15M1/0120

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J	93.1806C.U.S.
EXAMINER	
AZPURU, C	
ART UNIT	PAPER NUMBER

1502  
DATE MAILED: 01/20/95

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on \_\_\_\_\_ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), \_\_\_\_\_ days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I. THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☒ Notice of References Cited by Examiner, PTO-892.
- ☒ Notice of Draftsman's Patent Drawing Review, PTO-848.
- ☐ Notice of Art Cited by Applicant, PTO-1449.
- ☐ Notice of Informal Patent Application, PTO-152.
- ☐ Information on How to Effect Drawing Changes, PTO-1474.
- ☐

Part II SUMMARY OF ACTION

- ☒ Claims 38-45 are pending in the application.  
Of the above, claims \_\_\_\_\_ are withdrawn from consideration.
- ☒ Claims 1-37 have been cancelled.
- ☐ Claims \_\_\_\_\_ are allowed.
- ☒ Claims 38-45 are rejected.
- ☐ Claims \_\_\_\_\_ are objected to.
- ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
- ☐ This application has been filed with Informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
- ☐ Formal drawings are required in response to this Office action.
- ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
- ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
- ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).
- ☒ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☒ been received ☐ not been received ☒ been filed in parent application, serial no. 07/786,400, filed on 11/20/91.
- ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
- ☐ Other

EXAMINER'S ACTION

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Art Unit: 1502

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### **Part III DETAILED ACTION**

Receipt is acknowledged of the preliminary amendment filed 10/24/95.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate description of the invention.

While the specification teaches improvement in nerve impulses, the claims appear to indicate a slowing of nerve conduction (See page 2, lines 5-24). Further, the specification appears to indicate that potassium ion flow is slowed, not nerve conduction. Clarification is requested.

1. Claims 38-45 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.
2. Claims 38-45 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims should refer to "said mono- or di-aminopyridine active agent" rather than "said active agent" in order to maintain proper antecedent basis. Correction is requested.

3. Claims 38-45 are rejected under 35 USC 112, sixth paragraph, as claiming a means or step for performing a specified function without the recital of structure, material, or acts in support thereof.

Specifically, applicant does not provide proper means/function by stating the effect of the release of the mono- or di-aminopyridine. It is suggested that the term "in need thereof" should be added after "patient".

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 38-41, and 45 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Davis et al, Bever et al., and Wesseling et al.

Both Davis et al. and Wesseling et al. disclose administration of 4-AP for improvement of neural conduction in MS (Davis et al.) and Alzheimer's (Wesseling et al). Further, Bever et al. teach that 3,4-DAP improves the response latencies in MS

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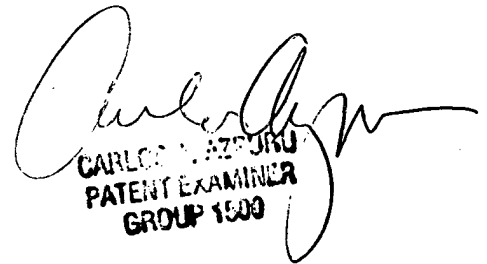
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patients. Both Davis et al. and Bever et al. teach multiple oral dosing, which is inclusive of applicant's stipulation of an effective dosage level between 12-24 hours. The claims are clearly anticipated.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos Azpuru whose telephone number is (703) 308-0237.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (703) 308-2927. The fax phone number for this Art Unit is (703) 305-5408.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-2351.

  
CARLOS AZPURU  
PATENT EXAMINER  
GROUP 1500